

REMARKS/ARGUMENTS

Claims 1-8 are pending in the present application. Claim 1 has been amended. Support for the above amendments can be found at paragraphs 0036 and 0068-0070.

The Examiner has rejected claims 1-8 under 35 U.S.C. § 112, second paragraph, as being indefinite, because the preamble of claim 1 refers to "venlafaxine", not an "acid addition salt of venlafaxine" as prepared in step b). In response, claim 1 has been amended in the preamble to replace the term "venlafaxine" to "acid addition salt of venlafaxine." Claims 2-8 depend from claim 1, and would therefor incorporate the amendment made to claim 1. It is respectfully requested that the rejection of claims 1-8 under 35 U.S.C. § 112, second paragraph, as being indefinite be withdrawn.

The Examiner also rejected claims 1-8 under 35 U.S.C. § 103 as unpatentable over Dolitzky et al. (WO 02/45658). The Examiner states that "it would have been obvious to a person having ordinary skill in the art to process with making the acid salt of venlafaxine without isolating the free base if the crystal of the venlafaxine salt that is ultimately produced by Dolitzky et al. is of sufficient purity for its intended use." See page 4, second paragraph of the Office Action. We respectfully traverse. Unlike the present invention, Dolitzky et al., discloses that prior to the reaction with an acid to make a venlafaxine salt, the venlafaxine base is isolated from its solution. Therefore, although the ultimately produced venlafaxine salt of Dolitzky has sufficient purity, one cannot conclude that the step of isolating venlafaxine base from its solution should be omitted. On the contrary, one would reasonably conclude that the isolation step is essential and cannot be omitted.

In our previous response, we amended claim 1 by reciting that the solution of venlafaxine is directly reacted to an acid to prepare an acid additional salt of venlafaxine to reflect that no isolation of solid venlafaxine base is conducted. However, in response, the Examiner states, "there is no limitation that positively excludes [a step of isolation of venlafaxine prior to making the acid salt]." See page 4 of the Office Action. We believe that the Examiner is incorrect in this regard. However, to make it clearer, claim 1 has been amended to indicate that the recited steps would inherently preclude the isolation of venlafaxine prior to making the acid salt -- in that the acid addition salt of venlafaxine is prepared from the organic venlafaxine solution that was produced in the prior extraction step.

The Examiner further states that the Dolitzky reference additionally teaches preparing venlafaxine free base, and further producing venlafaxine hydrochloride by exposing a mixture of venlafaxine in acetone to gaseous hydrochloric acid. See page 3 of the Office Action.

Claim 1, as amended, is distinguished from this disclosure of Dolitzky in that a water-immiscible organic solvent is used to extract the venlafaxine from the aqueous solution, and the conversion of the venlafaxine to venlafaxine hydrochloride is conducted in the same water-immiscible organic solvent. In contrast, Dolitzky discloses the use of acetone or isopropyl alcohol in converting the venlafaxine to venlafaxine hydrochloride. See page 4, lines 1-4 and Figure 10 of Dolitzky. Both acetone or isopropyl alcohol are miscible in water, and would not be used in the presently claimed process.

In view of the claim amendment and the above-discussed differences between the claimed process and Dolitzky, it is respectfully requested that the rejection of claims 1-8 as 8 under 35 U.S.C. § 103 as unpatentable over Dolitzky be withdrawn.

Accordingly, it is respectfully submitted that the claims, as amended, are now in a condition for allowance, early notice of which is earnestly solicited.

If any additional fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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